VISX®

Treating Decentered Ablations Using the VISX Custom-CAP™ Method and the Zeiss Humphrey® Systems VisionPro™ Ablation Planner

HUMANITARIAN DEVICE. Authorized by U.S. Federal Law for use in the treatment of symptomatic decentered ablations from previous laser surgery. The effectiveness of this device for this use has not been demonstrated.

15

02-128

Revision Record — 0030-3027

Treating Decentered Ablations Using Custom-CAP™ Method and Zeiss Humphrey VisionPro

Revision	Description	Date	ECN #
A	Custom-CAP Instructions for Decentered Ablations	03/18/02	8245

02-130

Instructions for Treating Decentered Ablations Using the VISX® Custom-CAP™ Method and the Zeiss Humphrey® Systems VisionPro™ Ablation Planner

1 Introduction

The condition of symptomatic asymmetrical ablation patterns resulting from decentered primary treatments has been found to occur in a very small percentage of patients who have undergone laser vision correction. These patients suffer from extreme visual discomfort and other associated visual disturbances including reduced visual acuity, excess glare, halos, and distorted visual effects. Experience in secondary treatments elsewhere demonstrates that improvements can occur when the laser is applied manually (although, with much less precision) to overcome extreme irregularities. Currently there are no software mechanisms available to treat these irregularities in a consistent manner. As a result additional undesirable secondary visual effects may occur after additional treatments are attempted.

VISX, Incorporated has developed a proprietary software algorithm, the Custom-CAP Method (Custom-Contoured Ablation Patterns), to reduce the symptoms associated with decentered ablations. As each patient requires an individually planned and created ablation based on the corneal topography, this surgery is customized and specific to each cornea. The device has the additional capability of relocating the primary optics aimed at the cornea to predefined locations off the central visual axis and onto the affected regions of the cornea. A specific algorithm uses various inputs to define the unique requirements of the decentered ablation in order to treat the symptoms associated with it and restore a more regular aspheric corneal shape.

The STAR S3 ActiveTrak™ Excimer Laser System integrates with the Zeiss Humphrey®* Systems VisionPro™† Ablation Planner to analyze the shape, location, size, and depth of decentered ablations from previous refractive laser surgery.

---

* Humphrey is a registered trademark of Zeiss Humphrey Systems.

† VisionPro is a trademark of Zeiss Humphrey Systems.

18

02-132

The vast majority of patients with normal corneal contours who receive small (<0.50 mm) decentered ablations experience no untoward symptoms. Patients with irregular corneal topographies who have an apparent decentration of the ablation pattern over the pupil and who suffer from visually related symptoms, including glare, disabling halos, and monocular diplopia, require additional treatment. A symptomatic decentration is defined as the combination of the symptoms (visual disturbances) and the signs (decentered ablation pattern as determined by the videokeratography unit).

2 Indications for Use

The Custom-CAP™ Method is indicated for the treatment of asymmetrical ablation patterns from previous laser refractive surgery caused by decentration of the treatment as viewed on the Zeiss Humphrey topography unit and treated with the STAR S3 ActiveTrak™ Excimer Laser System in patients:

- who exhibit symptomatology supportive of visual defect: reduced best spectacle-corrected visual acuity, debilitating glare, monocular diplopia (double vision), and/or debilitating halos.
- who pre-operatively have at least a 6 µm difference on the elevation topography, from the lowest point to the highest point, over a 6.5 mm diameter or over the patient's pupil diameter as measured by the Zeiss Humphrey topographer, whichever is larger.

2.1 Contraindications

Treatment using the Custom-CAP Method is contraindicated:

- in patients with abnormally thin corneas or in patients where the anticipated treatment would violate the posterior 280 microns (µm) of corneal stroma.
- in patients with collagen vascular, autoimmune, or immunodeficiency diseases.
- in pregnant or nursing women.
- in patients with signs of keratoconus or suspected keratoconus.
- in patients who are taking one or both of the following medications: Isotretinoin (Accutane®*); amiodarone hydrochloride (Cordarone®†).

---

* Accutane is a registered trademark of Hoffmann-La Roche Inc.

† Cordarone is a registered trademark of Sanofi.

2.2 Warnings

- The Custom-CAP™ Method has not been validated for the treatment of corneas with decentered ablations.
- Using the Custom-CAP Method to treat decentered ablations from previous laser refractive surgery may produce a decrease in vision and/or an increase in corneal irregularity.
- Using the Custom-CAP Method to treat decentered ablations from previous laser refractive surgery may increase the likelihood of additional corrective surgery.

WARNING! The post-simulation elevation range should be smaller than the pre-operative elevation range for all Custom-CAP treatments.

- The Custom-CAP Method is intended to improve best spectacle-corrected visual acuity. Refractive results after a Custom-CAP treatment will vary. Surgeons are warned NOT to combine a refractive treatment with Custom-CAP during the same surgery.
- Surgeons are warned NOT to combine a PTK treatment with Custom-CAP during the same surgery.
- The decision to perform laser refractive surgery in patients with systemic disease likely to affect wound healing, such as connective tissue disease, diabetes, severe atopic disease, or an immunocompromised status, should be approached cautiously. The safety and effectiveness of the STAR S3 ActiveTrak™ System has not been established in patients with these conditions.
- Laser refractive surgery is not recommended in patients with a history of ophthalmic *Herpes simplex* or *Herpes zoster.*
- Lower uncorrected visual acuity rates of 20/20 and 20/40 may be anticipated with higher degrees of correction of myopia and astigmatism.

2.3 Precautions

- Surgeons need to be aware of the potential for increased risk of corneal haze post-treatment when using a PRK treatment plan with the Custom-CAP Method.
- Using the Custom-CAP Method to treat decentered ablations from previous laser refractive surgery may produce a decrease in visual acuity or may increase corneal irregularity.

- The Custom-CAP™ Method is not restricted to PRK or LASIK procedures for prior PRK or LASIK patients. This is a surgeon-driven decision.

2.4 PRK Adverse Events

There was no patient death related to the use of the STAR S3 ActiveTrak™ System.

The following transient complications might be expected with patients undergoing the PRK procedure: pain (1 to 4 days), foreign body sensation, tearing, photophobia, redness, itching/scratchiness, burning, dryness, headache, blurred vision, corneal swelling, and pupil enlargement.

Other adverse events that might be expected with patients undergoing the PRK procedure but have not been observed in the VISX® clinical studies are corneal perforations, intraocular infections, hyphemas, hypopyon, post-treatment lens abnormalities with vision loss, significant overcorrections, persistent corneal decompensation/edema, or cystoid macular edema.

Excimer laser energy has the potential to induce micromechanical damage to endothelial cells, induce cataracts, and cause mutations. These effects have not been observed in any clinical use, nor have they been reproducible in various animal and *in vitro* test systems.

2.5 LASIK Adverse Events

There was no patient death related to the use of the STAR S3 ActiveTrak System.

Studies in which LASIK was performed demonstrated no adverse events for corneal infiltrates or ulcer; melting of the flap; late onset of haze; retinal detachment; or retinal vascular accidents.

At 3 months post-operatively, patients treated for myopia with or without astigmatism reported glare (6%), severe halos (4%), and/or severe fluctuations of vision (2%).